Examples

Of

Form Modules

TREATMENT PHASE ACTIVITIES

Patient initials: _ _ _

PROTOCOL

Patient number: _ _ _ _ _

ACTIVITY	STUDY PERIOD										
	INITIAL SCREEN	SECOND SCREEN[b]	DAY 1[a,c]	WEEK 2	WEEK 4	WEEK 8	WEEK 12	WEEK 16	WEEK 20	WEEK 24	EARLY D/C
Informed Consent	X										
Eligibility Criteria	page 1	page 11									
Medical History & Baseline Condition		pages 13-14									
HIV History	pages 3-8										
History of Current Illness	page 9										
Antiretroviral & Immunomodulator Hx[d]	page 10										
Visit Report: Demography	page 2										
Vital Signs		page 12	page 17	page 21	page 25	page 29	page 33	page 37	page 40	page 43	page 48
Study Medication			page 17	page 21	page 25	page 29	page 33	page 37	page 40	page 43	page 48
ECG / Chest X-Ray		page 12									
Physical Examination[e]		pages 15-16	pages 18-19	pages 22-23	pages 26-27	pages 30-31	pages 34-35	pages 38-39	pages 41-42	pages 44-45	pages 49-50
Pharmacokinetics[h]			page 20	page 24	page 28	page 32	page 36			page 46	page 51
Fecal Occult Blood		page 65	page 65[g]	page 65[g]	page 65[g]	page 65[g]	page 65[g]	page 65[g]	page 65[g]	page 65[g]	page 65[g]
Hep B/C		X									
Hematology		X	X	X	X	X	X	X	X	X	X
Chemistries		X	X[f]	X	X	X	X[f]	X	X	X[f]	X[f]
Urinalysis		X	X	X	X	X	X	X	X	X	X
Serum Pregnancy		X	X	X	X	X	X	X	X	X	X
CD4/CD8	X	X	X	X	X	X	X	X	X	X	X
HIV-1 RNA PCR	X	X	X	X	X	X	X	X	X	X	X
Gen/Phen			X							X	X
Treatment Termination Report										page 47	page 47
Adverse Event Form			**DURING *TREATMENT*** pages 66-75								
Concomitant Medication			**DURING *TREATMENT*** pages 76-78								
Serious Adverse Event Report Form			**SERIOUS EVENTS ONLY**								
Adverse Event Follow - Up			**POST-STUDY:** *ALL CONTINUING EVENTS WHICH ARE SERIOUS OR POSSIBLY RELATED TO STUDY MEDICATION* pages 79-83								

[a] Within 21 days of INITIAL SCREEN

[b] DAY (-14) to DAY (-2)

[c] All activities at this visit are to be performed before patient dosing

[d] Assessment of antiretroviral agents available for treatment switch

[e] Include all HIV-related, toxicity-related, and AIDS-defining events, including signs/symptoms

[f] Fasting specimen

[g] Only if indicated

[h] Plasma and concentrations and trough concentrations

HEADER (Module 1) (Fixed) *FOR THE FIRST PAGE PER VISIT (PRE-RANDOMIZATION)*

97-XXXX-XXX **STUDY PERIOD**

Center number: _ _ _ _ _ Patient initials: _ _ _ Patient number: _ _ _ _ _

Date of birth: _ _ _ _ - _ _ - _ _ (y y y y - m m - d d) Date of visit: _ _ _ _ - _ _ - _ _ (y y y y - m m - d d)

☐ *Data added after WORKING COPY (yellow) has been submitted* ☐ *Page not done*

HEADER (Module 2) (Fixed) *SUBSEQUENT CRFs (PRE-RANDOMIZATION)*

97-XXXX-XXX **STUDY PERIOD**

Center number: _ _ _ _ _ Patient initials: _ _ _ Patient number: _ _ _ _ _

Date of birth: _ _ _ _ - _ _ - _ _ (y y y y - m m - d d)

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HEADER (Module 3) (Fixed) *FOR THE FIRST PAGE PER VISIT (POST-RANDOMIZATION)*

97-XXXX-XXX **STUDY PERIOD**

Center number: _ _ _ _ _ Patient initials: _ _ _ Patient number: _ _ _ _ _

Date of visit: _ _ _ _ - _ _ - _ _ (y y y y - m m - d d)

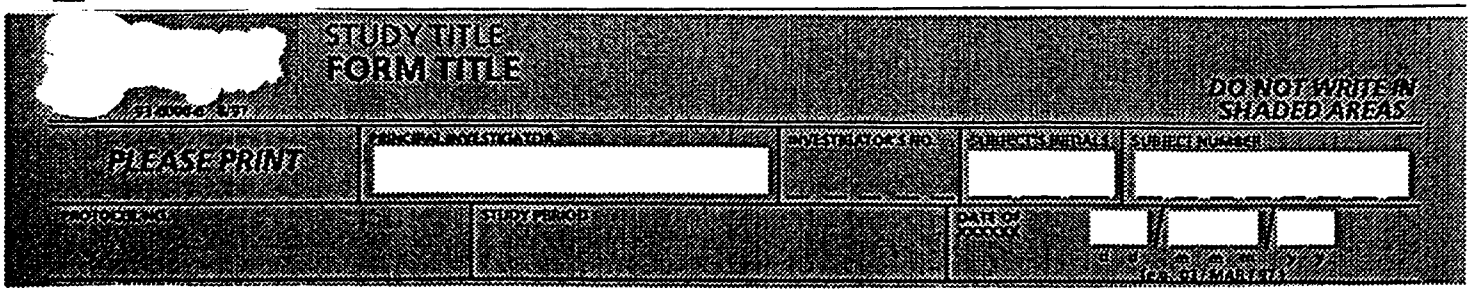
☐ *Data added after WORKING COPY (yellow) has been submitted* ☐ *Page not done*

HEADER (Module 4) (Fixed) *SUBSEQUENT CRFs (POST-RANDOMIZATION)*

97-XXXX-XXX **STUDY PERIOD**

Center number: _ _ _ _ _ Patient initials: _ _ _ Patient number: _ _ _ _ _

☐ *Data added after WORKING COPY (yellow) has been submitted* ☐ *Page not done*



FOOTER (Module 1) (Fixed) *TO APPEAR ONCE PER VISIT*

I hereby confirm that the data contained on pages X - Y (pages for one study period eg, VISIT 1) are correct and complete to the best of my knowledge.

Investigator's signature: ..... Date of signature: _ _ _ _ - _ _ - _ _
y y y y m m d d

CRF VERSION IDENTIFIERS

FOOTER (Module 2) (Fixed) *ALL OTHER CRFs*

CRF VERSION IDENTIFIERS

INITIALS or SIGNATURE:		SHEET NO.	1

I verify that informed consent has been obtained as specified in the protocol for this subject to participate in this study; AND that this subject: *(check one)*:

- ☐ meets all protocol requirements and may be entered into this study
- ☐ does not meet all protocol requirements and will not be entered into this study*

* specify reason(s)/rationale under "COMMENTS" below

COMMENTS:

INVESTIGATOR'S SIGNATURE:		d d / m m / y y	SHEET NO.	1

ELIGIBILITY CRITERIA (Module 1) (Protocol Specific)

INCLUSION CRITERIA:

	Yes	No
1. Protocol Inclusion Criteria number one text here [(☐ Not Applicable)]		STOP
2. Protocol Inclusion Criteria number two text here [(☐ Not Applicable)]		STOP
3. Protocol Inclusion Criteria number three text here [(☐ Not Applicable)]		STOP

Any "No" response in the above section disqualifies this patient from study participation.

EXCLUSION CRITERIA:

	Yes	No
1. Protocol Exclusion Criteria number one text here [(☐ Not Applicable)]	STOP	
2. Protocol Exclusion Criteria number two text here [(☐ Not Applicable)]	STOP	
3. Protocol Exclusion Criteria number three text here [(☐ Not Applicable)]	STOP	

Any "Yes" response in the above section disqualifies this patient from study participation.

DEMOGRAPHICS

SEX	DATE OF BIRTH	RACE (Check one box)
☐ 1 Male ☐ 2 Female	d d / m m m / y y	☐ 1 White ☐ 2 Black ☐ 3 Asian or Pacific Islander ☐ 4 Mixed

SEX	DATE OF BIRTH	RACE (Check one box)
☐ 1 Male ☐ 2 Female	d d / m m m / y y	☐ 0 Not allowed to ask per local regulations ☐ 1 White ☐ 2 Black ☐ 3 Asian or Pacific Islander ☐ 4 Mixed

(For collection of National / Ethnic Origins) EXAMPLE:

Hispanic?	☐ 1 Yes	☐ 0 No
American Indian?	☐ 1 Yes	☐ 0 No
Aleutian Islander or Eskimo?	☐ 1 Yes	☐ 0 No

Data Module: **Vital signs**

HEIGHT (without shoes) ___.__ ☐ 1 cm ☐ 2 in

WEIGHT (without shoes) ___.__ ☐ 1 kg ☐ 2 lb

BODY BUILD ☐ 1 Small ☐ 2 Medium ☐ 3 Large

BODY SURFACE AREA ___.____ m^2

BODY MASS INDEX ___.__ kg/m^2

BLOOD PRESSURE ___ / ___ mm Hg (SYS / DIAS) ☐ 1 Sitting ☐ 2 Standing ☐ 3 Supine

TEMPERATURE ___.__ ☐ 1 °C ☐ 2 °F ☐ 1 Oral ☐ 2 Rectal ☐ 3 Axillary ☐ 4 Aural ☐ 5 Core

PULSE ___ /min ☐ 1 Sitting ☐ 2 Standing ☐ 3 Supine ☐ 1 Regular ☐ 2 Irregular

RESPIRATION RATE ___ /min

Were any clinically significant changes observed since the last examination?

☐ 0 No ☐ 1 Yes IF YES, SPECIFY UNDER "COMMENTS" BELOW

If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).

COMMENTS:

STUDY PERIOD	DATE & TIME (dd/mm/yy) (01/01/90)	WEIGHT (without shoes)	BLOOD PRESSURE (Sys/Dias) (mmHg)	TEMPERATURE ☐ 1 °C ☐ 2 °F	PULSE (/min)	RESPIRATION (/min)
1	__/__/__ ____	____.__ ☐ 1 kg ☐ 2 lb	___ / ___ ☐ 1 Sitting ☐ 2 Standing ☐ 3 Supine	____.__ ☐ 1 Oral ☐ 2 Rectal ☐ 3 Axillary ☐ 4 Aural ☐ 5 Core	___ ☐ 1 Regular ☐ 2 Irregular ☐ 1 Sitting ☐ 2 Standing ☐ 3 Supine	___
2	__/__/__ ____	____.__ ☐ 1 kg ☐ 2 lb	___ / ___ ☐ 1 Sitting ☐ 2 Standing ☐ 3 Supine	____.__ ☐ 1 Oral ☐ 2 Rectal ☐ 3 Axillary ☐ 4 Aural ☐ 5 Core	___ ☐ 1 Regular ☐ 2 Irregular ☐ 1 Sitting ☐ 2 Standing ☐ 3 Supine	___
3	__/__/__ ____	____.__ ☐ 1 kg ☐ 2 lb	___ / ___ ☐ 1 Sitting ☐ 2 Standing ☐ 3 Supine	____.__ ☐ 1 Oral ☐ 2 Rectal ☐ 3 Axillary ☐ 4 Aural ☐ 5 Core	___ ☐ 1 Regular ☐ 2 Irregular ☐ 1 Sitting ☐ 2 Standing ☐ 3 Supine	___

Were any clinically significant changes observed at these examinations?

☐ 0 No ☐ 1 Yes IF YES, SPECIFY UNDER "COMMENTS" BELOW

If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).

COMMENTS:

VITAL SIGNS (Module 2 - Log Format Example) (Fixed & Optional)

Study Period	Date (yyyy-mm-dd)	Time (0001-2400)	Weight (kilograms)	Sitting Blood Pressure (Systolic/Diastolic)	Sitting Pulse (/min)	Oral Temperature (°C)
VISIT 1	_ _ _ _ - _ _ - _ _	_ _ _ _	_ _ _ . _	_ _ _ / _ _ _	_ _ _	_ _ _ . _
VISIT 2	_ _ _ _ - _ _ - _ _	_ _ _ _	_ _ _ . _	_ _ _ / _ _ _	_ _ _	_ _ _ . _
VISIT 3	_ _ _ _ - _ _ - _ _	_ _ _ _	_ _ _ . _	_ _ _ / _ _ _	_ _ _	_ _ _ . _
VISIT 4	_ _ _ _ - _ _ - _ _	_ _ _ _	_ _ _ . _	_ _ _ / _ _ _	_ _ _	_ _ _ . _

General Appearance:

INSTRUCTIONS: Check appropriate box to indicate current physical examination findings. Describe any abnormalities, indicating left or right where applicable. If evaluation of the category is not performed, write "Not Done".

PHYSICAL FINDINGS

1. HEAD AND NECK	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
2. ENT / MOUTH	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
3. CHEST / LUNGS	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
4. HEART	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
5. BREASTS	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
6. BACK / SPINE	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
7. ABDOMEN	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
8. GENITALIA	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
9. RECTUM	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
10. EXTREMITIES	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
11. SKIN	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
12. LYMPH NODES	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
13. NERVOUS SYSTEM	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
14. MENTATION	☐ 0 Normal ☐ 1 Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE:
IF DESCRIBE ANY OTHER ABNORMAL PHYSICAL FINDINGS:		

Were any clinically significant changes observed since the last examination?

☐ 0 No ☐ 1 Yes IF YES, SPECIFY CATEGORY AND FINDINGS UNDER "COMMENTS" BELOW

If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).

COMMENTS:

INSTRUCTIONS: Check appropriate box(es) to indicate medical history of disorders in the areas listed below. Include any surgeries or hospitalizations under appropriate category. Describe or comment if "History" or "Present Condition" is checked.

MEDICAL HISTORY

	DESCRIBE / COMMENT
16 HEENT / MOUTH ☐ 0 None ☐ 1 History ☐ 2 Present condition	
1 CARDIOVASCULAR ☐ 0 None ☐ 1 History ☐ 2 Present condition	
2 PULMONARY ☐ 0 None ☐ 1 History ☐ 2 Present condition	
3 GASTROINTESTINAL ☐ 0 None ☐ 1 History ☐ 2 Present condition	
4 HEPATOBILIARY ☐ 0 None ☐ 1 History ☐ 2 Present condition	
7 RENAL / URINARY TRACT ☐ 0 None ☐ 1 History ☐ 2 Present condition	
8 REPRODUCTIVE / GENITALIA ☐ 0 None ☐ 1 History ☐ 2 Present condition	
12 MUSCULOSKELETAL ☐ 0 None ☐ 1 History ☐ 2 Present condition	
5 NEUROLOGIC (including convulsive disorders) ☐ 0 None ☐ 1 History ☐ 2 Present condition	
17 DERMATOLOGIC ☐ 0 None ☐ 1 History ☐ 2 Present condition	
11 METABOLIC / ENDOCRINE ☐ 0 None ☐ 1 History ☐ 2 Present condition	
6 HEMATOLOGIC ☐ 0 None ☐ 1 History ☐ 2 Present condition	
10 IMMUNOLOGIC ☐ 0 None ☐ 1 History ☐ 2 Present condition	
4 PSYCHIATRIC ☐ 0 None ☐ 1 History ☐ 2 Present condition	
13 NEOPLASTIC ☐ 0 None ☐ 1 History ☐ 2 Present condition	
19 ALLERGIC ☐ 0 None ☐ 1 History ☐ 2 Present condition	
OTHER (specify) ☐ 1 History ☐ 2 Present condition	

This module contains the previous and the current medical history of the patient. According to the protocol the history is within a certain period (ie, 10 days, 3 months, ..)

- **Diagnosis:** Record all medical conditions for the specified System Organ Class being evaluated since xxxx years and all current physical findings.

- **Status at BASELINE:** Tick only one of the following boxes for each diagnosis:

  - Past: If condition is not present anymore.

  - Under Control: If condition is currently present without any signs or symptoms (eg, drug-controlled hypertension, diet controlled diabetes, stable multiple sclerosis)

  - Active: If signs or symptoms of condition are currently present.

- **Dates:** Record all dates as completely as possible in the yyyy-mm-dd format. Example : 1997-09-30 It is both acceptable and preferable to estimate dates when exact dates cannot be provided. Wherever this is done, write "estimated" by the corresponding date. If the date is completely unknown, then write "unknown" in the date space so the Pharmacia & Upjohn monitor will know the date is truly missing and not just overlooked.

- **Describe Medical History and/or Results of Physical Examination:** Additional information about the diagnosis may be added.

MEDICAL HISTORY AND BASELINE CONDITION (Module 1) (Fixed & Optional)

Date of Assessment: __ __ __ __ - __ __ - __ __
y y y y m m d d

Examine/review the following System Organ Classes [(including/excluding condition being treated in this study)]:

- Ear & labyrinth disorders
- Eye disorders
- Cardiac disorders
- Respiratory, thoracic & mediastinal disorders
- Gastrointestinal disorders
- Hepato-biliary disorders
- Renal & urinary disorders
- Reproductive system & breast disorders
- Musculoskeletal, connective tissue & bone disorders
- Neurological disorders
- Skin & subcutaneous tissue disorders
- Metabolism & nutrition disorders
- Endocrine disorders
- Blood & lymphatic system
- Vascular disorders
- Immune system disorders
- Psychiatric disorders
- Benign & malignant neoplasms (including cysts & polyps)
- Infections & infestations
- Congenital & familial/genetic disorders
- General disorders
- Surgical & medical procedures
- Injury & poisoning
- Investigations
- Pregnancy, puerperium & perinatal conditions
- Social circumstances

Are there any history and/or physical findings?

If No, tick "No" box and skip this section. Otherwise, complete this section. ☐0 No

Diagnosis	Status at BASELINE (tick only one) Past	Under Control	Active	Start Date (yyyy-mm-dd) Stop Date (yyyy-mm-dd)	Describe Medical History and/or Results of Physical Examination
	☐1	☐2	☐3	____-__-__ ____-__-__	
	☐1	☐2	☐3	____-__-__ ____-__-__	
	☐1	☐2	☐3	____-__-__ ____-__-__	
	☐1	☐2	☐3	____-__-__ ____-__-__	
	☐1	☐2	☐3	____-__-__ ____-__-__	
	☐1	☐2	☐3	____-__-__ ____-__-__	
	☐1	☐2	☐3	____-__-__ ____-__-__	
	☐1	☐2	☐3	____-__-__ ____-__-__	

CHECK BOX IF TEST NOT DONE →

HEMATOLOGY

URINALYSIS

CHECK BOX IF TEST NOT DONE →

CHEMISTRIES

Did any unfavorable or unintended *clinically significant* change in laboratory data occur?

☐$_0$ No
☐$_1$ Yes

If Yes, complete a MEDICAL EVENT FORM (MEF).

	CHECK BOX IF TEST NOT DONE		
STUDY PERIOD:			
DATE SPECIMENS TAKEN:	MO. ___ / DAY ___ / YEAR ___	MO. ___ / DAY ___ / YEAR ___	MO. ___ / DAY ___ / YEAR ___
HEMATOLOGY			
URINALYSIS			
CHEMISTRIES			
Did any unfavorable or unintended *clinically significant* change in laboratory data occur?	☐$_0$ No ☐$_1$ Yes*	☐$_0$ No ☐$_1$ Yes*	☐$_0$ No ☐$_1$ Yes*

* If Yes, complete a MEDICAL EVENT FORM (MEF)

COMPLETE BLOOD COUNT

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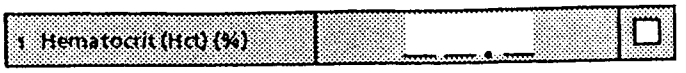

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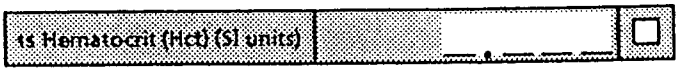

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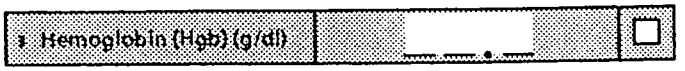

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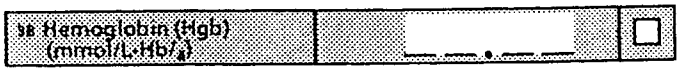

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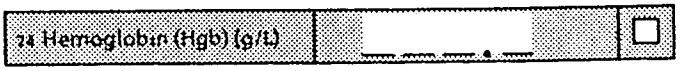

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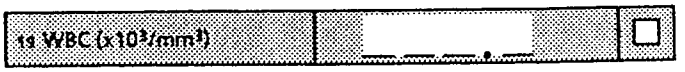

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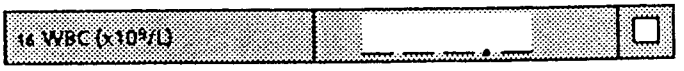

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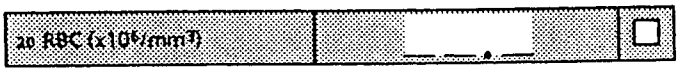

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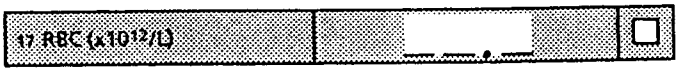

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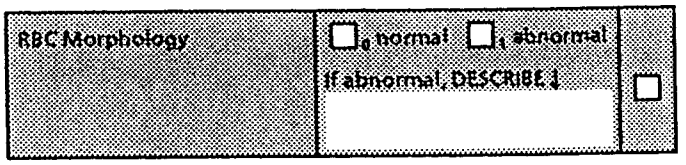

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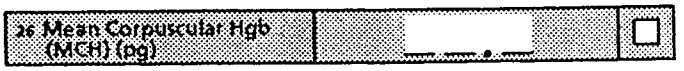

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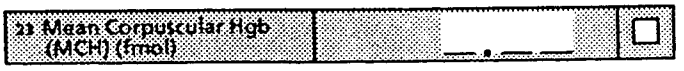
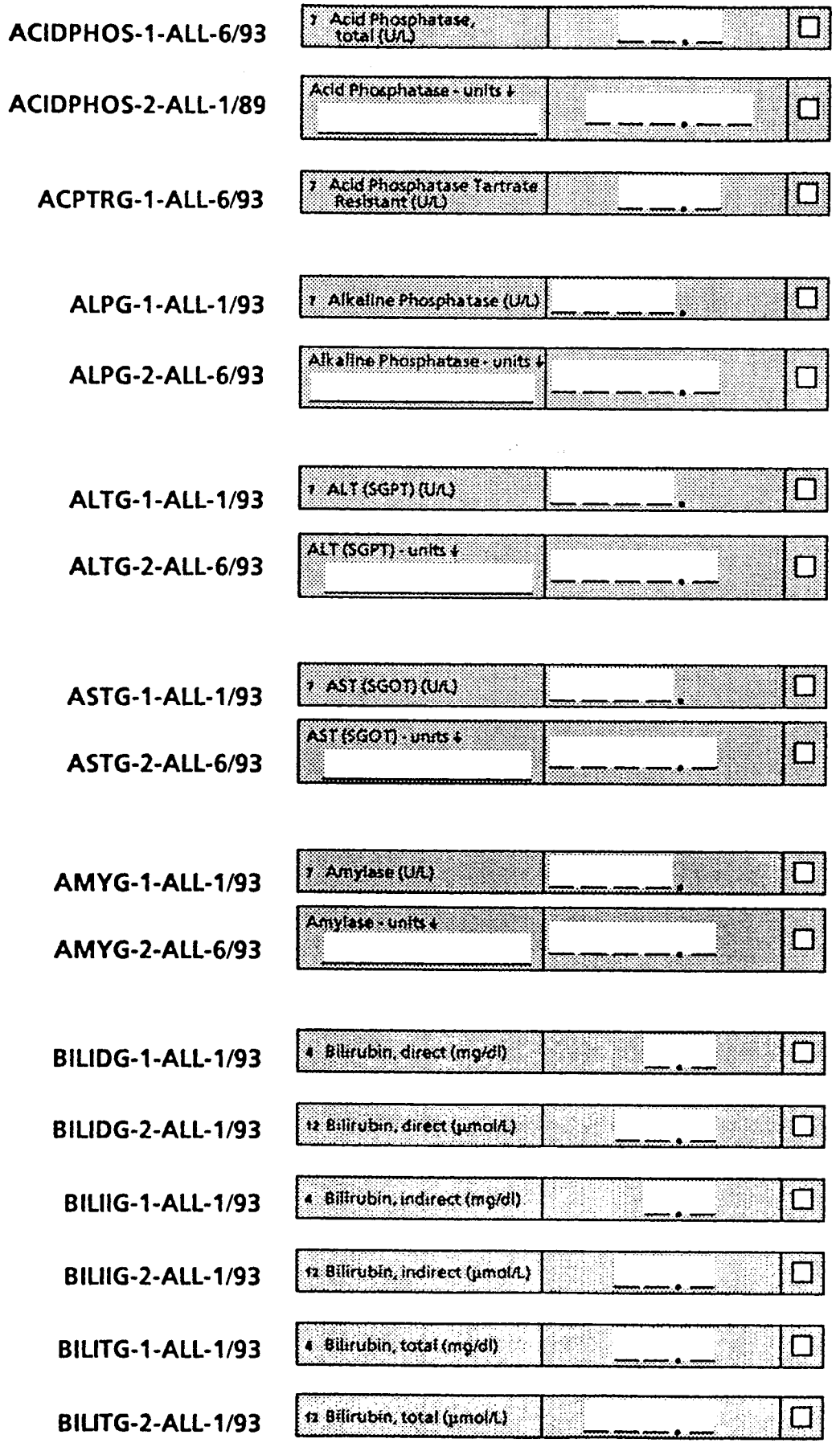


GENERAL CHEMISTRIES



X-RAY (Module 1) (Fixed & Optional) *(before patient has received any study medication)*

Date of X-ray: $\underline{y}\ \underline{y}\ \underline{y}\ \underline{y}$ - $\underline{m}\ \underline{m}$ - $\underline{d}\ \underline{d}$

Location: _____

Result:

- ☐ 1 Normal
- ☐ 2 Abnormal, not clinically relevant
- ☐ 3 Abnormal, clinically relevant ⟶ **Record on *History & Baseline Condition* page**

X-RAY (Module 2) (Fixed & Optional) *(after patient has received at least one dose of study medication)*

Date of X-ray: $\underline{y}\ \underline{y}\ \underline{y}\ \underline{y}$ - $\underline{m}\ \underline{m}$ - $\underline{d}\ \underline{d}$

Location: _____

Result:

- ☐ 1 Normal
- ☐ 2 Abnormal, not clinically relevant
- ☐ 3 Abnormal, clinically relevant ⟶ **Fill in / update an *Adverse Event* page**

EKG

Rhythm:
- ☐ 0 Normal
- ☐ 1 PAC's
- ☐ 2 PVC's
- ☐ 3 Atrial flutter
- ☐ 4 Sinus tach
- ☐ 5 Sinus brad
- ☐ 6 VT
- ☐ 7 Pacemaker
- ☐ 8 PVC's: Unifocal
- ☐ 9 PVC's: Multifocal
- ☐ 10 PVC's: Couplets
- ☐ 11 V Fib
- ☐ 12 A Fib
- ☐ 13 Atrial cycle length ____ msec
- ☐ Other, specify:

AV Conduction:
- ☐ 0 Normal (1 : 1)
- ☐ 1 2 : 1
- ☐ 2 3 : 1
- ☐ 3 4 : 1
- ☐ 4 3° block or AV dissoc
- ☐ Other, specify:

P Wave:
- ☐ 0 Normal
- ☐ 1 RAE
- ☐ 2 LAE
- ☐ 3 BAE
- ☐ Other, specify:

Q Wave:
- ☐ 0 Absent or normal
- ☐ 1 Diagnostic of infarct
- ☐ Other, specify:

QRS:
- ☐ 0 Normal
- ☐ 1 RBBB
- ☐ 2 LBBB
- ☐ 3 LAH
- ☐ 4 RVH
- ☐ 5 LVH
- ☐ Other, specify:

T Wave:
- ☐ 0 Normal
- ☐ 1 Peaked
- ☐ 2 Flat
- ☐ 3 Inverted
- ☐ Other, specify:

Lead:

ST segment

Value (mm): + ☐ or − ☐ ___.___

Lead:

Interpretation:
- ☐ 0 Normal
- ☐ 1 Infarct/ischemia
- ☐ 2 RV strain
- ☐ 3 LV strain
- ☐ 4 Digoxin toxicity
- ☐ 5 Nonspecific
- ☐ Other, specify:

Was acute myocardial ischemia suggested?
- ☐ 0 No
- ☐ 1 Yes, specify diagnosis(es)
  - ☐ 1 Acute transmural
  - ☐ 2 Acute subendocardial
  - ☐ Other, specify:

Was acute myocardial infarction suggested?
- ☐ 0 No
- ☐ 1 Yes, specify location(s)
  - ☐ 1 Anterior
  - ☐ 2 Posterior
  - ☐ 3 Lateral
  - ☐ 4 Septal
  - ☐ 5 Inferior
  - ☐ Other, specify:

Was "old" myocardial infarction suggested?
- ☐ 0 No
- ☐ 1 Yes, specify location(s)
  - ☐ 1 Anterior
  - ☐ 2 Posterior
  - ☐ 3 Lateral
  - ☐ 4 Septal
  - ☐ 5 Inferior
  - ☐ Other, specify:

PLEASE ATTACH ECG TRACING

COMMENTS:

EXAMPLE 1

Start date	Stop date	Dosage
y y y y - m m - d d	y y y y - m m - d d	___ tablets per day

EXAMPLE 2

Start date and time	Stop date and time	Dosing regimen		
		Amount	Units	Frequency
y y y y - m m - d d (0001 - 2400)	y y y y - m m - d d (0001 - 2400)	____	____	____

EXAMPLE 3

Day	Date	Dose #	Time *(0001-2400)*	Number of Tablets	Strength *(mg/tab)*
1	y y y y - m m - d d	1	_ _ _ _	____	☐300 ☐600
		2	_ _ _ _	____	☐300 ☐600
		3	_ _ _ _	____	☐300 ☐600

EXAMPLE 4 (Infusions)

Dose #	Start date and time	Stop date and time	Rate *(mg/kg/min)*	Weight *(kg)*
1	y y y y - m m - d d (0001 - 2400)	y y y y - m m - d d (0001 - 2400)	____	_ _ _ • _

INITIAL

NON-INVESTIGATIONAL MEDICATION

Has subject taken any non-investigational medication during the past XXXXXX? ☐ No

If No, check box and skip this section. If Yes, complete this section. PLEASE PRINT

MEDICATION TRADE OR GENERIC NAME For generic products with multiple active ingredients, list all on one line.	DATE & TIME STARTED (dd/mmm/yy) (0001-2400)	TO BE CONTINUED?	IF NO, DATE & TIME STOPPED (dd/mmm/yy) (0001-2400)	DOSING REGIMEN AMOUNT per dose	DOSING REGIMEN UNITS	DOSING REGIMEN FREQ.	ROUTE OF ADMIN.	REASON FOR USE OF MEDICATION (MAJOR DIAGNOSIS)
EXAMPLE ADVIL (or ibuprofen)	10/JUN/97 0500	☐ 0 NO ☒ 1 YES	__/__/__ __ __ __ __	600	mg	QID	PO	joint pain in left shoulder
EXAMPLE chlorthalidone, reserpine	07/AUG/97 0800	☒ 0 NO ☐ 1 YES	29/AUG/97 1600	50 0.25	mg	QD	PO	hypertension
1.	__/__/__ __ __ __ __	☐ 0 NO ☐ 1 YES	__/__/__ __ __ __ __					
2.	__/__/__ __ __ __ __	☐ 0 NO ☐ 1 YES	__/__/__ __ __ __ __					

FOLLOW-UP

NON-INVESTIGATIONAL MEDICATION

Have there been any CHANGES since the last report? ☐ No

If No, check box and skip this section. If Yes, complete this section. PLEASE PRINT

MEDICATION TRADE OR GENERIC NAME For generic products with multiple active ingredients, list all on one line.	ACTION TAKEN	DATE OF ACTION (dd/mmm/yy)	TIME OF ACTION (0001-2400)	DOSING REGIMEN AMOUNT per dose	DOSING REGIMEN UNITS	DOSING REGIMEN FREQ.	ROUTE OF ADMIN.	* REASON FOR ACTION (MAJOR DIAGNOSIS)
EXAMPLE ADVIL (or ibuprofen)	☐ 1 START ☐ 2 STOP ☒ 3 CHANGE IN DOSE ☐ 4 SINGLE DOSE	07/FEB/98	UNKNOWN	400	mg	QID	PO	joint pain in left shoulder
EXAMPLE chlorthalidone, reserpine	☒ 1 START ☐ 2 STOP ☐ 3 CHANGE IN DOSE ☐ 4 SINGLE DOSE	17/FEB/98	UNKNOWN	50 0.25	mg	QD	PO	hypertension
1.	☐ 1 START ☐ 2 STOP ☐ 3 CHANGE IN DOSE ☐ 4 SINGLE DOSE	__/__/__						
2.	☐ 1 START ☐ 2 STOP ☐ 3 CHANGE IN DOSE ☐ 4 SINGLE DOSE	__/__/__						

* If any of these are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).

INITIAL

NON-MEDICATION THERAPY (Any therapy or procedure that does not involve medication)

Have any non-medication therapies or procedures been administered to the subject during the past XXXXXX? ☐ No

If No, check box and skip this section. If Yes, complete this section.

THERAPY / PROCEDURE	DATE & TIME STARTED (dd/mmm/yy) (0001-2400)	TO BE CONTINUED?	IF NO, DATE & TIME STOPPED (dd/mmm/yy) (0001-2400)	REASON FOR USE OF THERAPY (MAJOR DIAGNOSIS)	COMMENTS
EXAMPLE DRAINAGE	07/AUG/97 0800	☒ 0 NO ☐ 1 YES	29/AUG/97 1800	ABSCESS	
1.	__/___/__ ____	☐ 0 NO ☐ 1 YES	__/___/__ ____		
2.	__/___/__ ____	☐ 0 NO ☐ 1 YES	__/___/__ ____		

FOLLOW-UP

NON-MEDICATION THERAPY (Any therapy or procedure that does not involve medication)

Have there been any CHANGES in non-medication therapies or procedures since the last report? ☐ No

If No, check box and skip this section. If Yes, complete this section.

THERAPY / PROCEDURE	ACTION TAKEN	DATE OF ACTION (dd/mmm/yy)	TIME OF ACTION (0001-2400)	* REASON FOR ACTION (MAJOR DIAGNOSIS)	COMMENTS
EXAMPLE OXYGEN	☐ 1 START ☐ 2 STOP ☒ 3 CHANGE (describe in COMMENTS)	07/AUG/97	1200	Pneumonia	Dosage increased to 8 l/min
1.	☐ 1 START ☐ 2 STOP ☐ 3 CHANGE (describe in COMMENTS)	__/___/__	____		
2.	☐ 1 START ☐ 2 STOP ☐ 3 CHANGE (describe in COMMENTS)	__/___/__	____		

* If any of these are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).

INSTRUCTIONS FOR ADVERSE EVENT FORM (AEF)

GENERAL INSTRUCTIONS

- Enter only events that occur during the adverse event reporting period specified on the AEF or in the protocol.

DEFINITION OF AN ADVERSE EVENT

- Untoward medical occurrence, whether or not considered related to the investigational medication, including:
  - suspected adverse reactions
  - reactions from: overdose, abuse, withdrawal, sensitivity, toxicity, [or failure of medication's expected pharmacologic action]
  - injury, reason for surgery, accidents, unrelated illness, worsening of preexisting illness
  - abnormal lab, physiological test, or physical exam finding requiring clinical intervention or further investigation (other than repeat test)
- Refer to adverse event section of protocol for additional information

SPECIFIC INSTRUCTIONS

- **Adverse Event** List syndrome (rather than individual symptoms) when appropriate; otherwise, list each symptom. Include adverse events identified on other forms (ie, Lab report, Physical examination, ECG, X-ray).
- **Start date [and time]** First appearance of this event (or worsening of preexisting illness) during the study. If continued from previous report, enter "cont".
- **Stop date [and time]** When event resolved. If ongoing, enter "cont".
- **[Nature of event**

1 = *Episodic*	Sometimes present, sometimes not.
2 = *Constant / single event*	Present continuously.
3 = *Chronic*	Not expected to resolve; need not be reported again unless intensity or relationship to investigational medication changes.]

- **Maximum intensity** Interference with subject's usual function:

1 = *Mild*	No interference.
2 = *Moderate*	Some interference.
3 = *Severe*	Significant interference.

- **Outcome to date** (as of date of evaluation at top of form)
  - 0 = *Recovered, no residual effects*
  - 1 = *Recovered, residual effects* (describe under COMMENTS)
  - 2 = *Continues*
  - 3 = *Death*
- **Was event serious?** See definition on form.

  NOTE: Notify Pharmacia & Upjohn monitor within 24 hours if serious adverse event occurs. Send completed AEF and AEFSI forms within 5 days.
- **Is there a reasonable possibility that the event was caused by investigational medication?** (0 = *No*, 1 = *Yes*)
- **Action taken with investigational medication due to this event**

0 = *None*	Includes cases where investigational medication stopped before event occurred.
1 = *Discontinued*	Permanently stopped.
[2 = *Reduced*	Dose decreased.]
3 = *Interrupted*	Temporarily stopped.
[4 = *Increased*	Withdrawal symptoms.]

- **Comments**

  Record only additional information which is relevant to and consistent with the adverse event(s) listed on the form.

STUDY TITLE

ADVERSE EVENT FORM (AEF)

DO NOT WRITE IN SHADED AREAS

PLEASE PRINT

PRINCIPAL INVESTIGATOR	INVESTIGATOR'S NO.	SUBJECT'S INITIALS	SUBJECT NUMBER
	___ ___ ___ ___		

PROTOCOL NO	STUDY PERIOD	DATE OF EVALUATION
___/___ ___ ___/___ ___ ___		d d / m m m / y y

Has subject had any adverse events since the last report?
If No, check box and go to next form. If Yes, complete this form. ☐ No

When completing this form, refer to the instruction page.
Carry forward any events that were continuing on the last report.

Adverse Event (DO NOT READ LIST TO SUBJECT)	Start date and time (dd/mmm/yy) (0001-2400)	Stop date and time (dd/mmm/yy) (0001-2400)	Nature of event (1 = Episodic, 2 = Constant / single event, 3 = Chronic)	Maximum intensity (1 = Mild, 2 = Moderate, 3 = Severe)	Outcome to date (0 = Recovered, no residual effects; 1 = Recovered, residual effects; 2 = Continues; 3 = Death)	Was event serious? *	Is there a reasonable possibility that the event was caused by investigational medication? (0 = No, 1 = Yes)	Action taken with investigational medication due to this event (0 = None, 1 = Discontinued, 2 = Reduced, 3 = Interrupted, 4 = Increased)
1.	__/___/___ ____	__/___/___ ____	___	___	___	☐0 No → ☐1 Yes → SKIP THESE 2 QUESTIONS, NOTIFY PHARMACIA & UPJOHN, AND COMPLETE AEFSI	___	___
2.	__/___/___ ____	__/___/___ ____	___	___	___	☐0 No → ☐1 Yes → SKIP THESE 2 QUESTIONS, NOTIFY PHARMACIA & UPJOHN, AND COMPLETE AEFSI	___	___
3.	__/___/___ ____	__/___/___ ____	___	___	___	☐0 No → ☐1 Yes → SKIP THESE 2 QUESTIONS, NOTIFY PHARMACIA & UPJOHN, AND COMPLETE AEFSI	___	___
4.	__/___/___ ____	__/___/___ ____	___	___	___	☐0 No → ☐1 Yes → SKIP THESE 2 QUESTIONS, NOTIFY PHARMACIA & UPJOHN, AND COMPLETE AEFSI	___	___
5.	__/___/___ ____	__/___/___ ____	___	___	___	☐0 No → ☐1 Yes → SKIP THESE 2 QUESTIONS, NOTIFY PHARMACIA & UPJOHN, AND COMPLETE AEFSI	___	___
6.	__/___/___ ____	__/___/___ ____	___	___	___	☐0 No → ☐1 Yes → SKIP THESE 2 QUESTIONS, NOTIFY PHARMACIA & UPJOHN, AND COMPLETE AEFSI	___	___

COMMENTS *(Record the event number for each comment):*

* *SERIOUS = Death, life-threatening, requires or prolongs in-patient hospitalization, persistent or significant disability/incapacity, permanent impairment of function or permanent damage to a body structure or requires intervention to prevent permanent impairment or damage, congenital anomaly/birth defect, or any other adverse event that the investigator or company judges to be serious or which is defined as serious by the regulatory agency in the country in which the adverse event occurred.*

RECORD MEDICATION AND NON-MEDICATION TREATMENT GIVEN FOR THE ADVERSE EVENT ON THE APPROPRIATE FORMS

INVESTIGATOR'S SIGNATURE: ___ d d / m m m / y y

MONITOR REVIEW BY: ___ d d / m m m / y y

SHEET NO 1

STUDY TITLE

ADVERSE EVENT FORM - SUPPLEMENTAL INFORMATION (AEFSI)

(USE TO SUPPLEMENT ADVERSE EVENT FORM (AEF) *FOR SERIOUS EVENTS ONLY*)

PRINCIPAL INVESTIGATOR	INVESTIGATOR'S NO.	SUBJECT'S INITIALS	SUBJECT NUMBER

PROTOCOL NO.	STUDY PERIOD	DATE OF EVALUATION
__/__ __ __ __/__ __ __ __		d d m m m y y (e.g., 05/MAR/98)

COUNTRY	PLEASE PRINT (DO NOT WRITE IN SHADED AREAS)	DATABASE NO.

ADVERSE EVENT:

(USE SAME TERMINOLOGY USED ON AEF)

Date event became serious: __/__/__ (d d m m m y y)

Time event became serious: ____ (0001-2400)

Reason Event is Serious
(CHECK ALL THAT APPLY)

- ☐ 1 Death → If subject died, complete *XXXX*.
- ☐ 2 Life-Threatening
- ☐ 3 Requires or Prolongs Hospitalization
- ☐ 4 Persistent or Significant Disability/Incapacity
- ☐ 5 Permanent Impairment/Damage
- ☐ 6 Requires Intervention to Prevent Permanent Impairment/Damage
- ☐ 8 Congenital Anomaly
- ☐ 97 Other

INVESTIGATIONAL MEDICATION

Medication Trade or Generic Name	Date Started (dd/mmm/yy)	Date Stopped (dd/mmm/yy)	DOSING REGIMEN Amount	Units	Freq.	Route of Admin.	Reason for Use (Major Diagnosis)	Action Taken (0 = None; 1 = Discontinued; 2 = Reduced; 3 = Interrupted; 4 = Increased)	Is there a reasonable possibility that the event was caused by this medication? (0 = No; 1 = Yes)	Main Investigator's Opinion	Did event abate after stopping medication? (0 = No; 1 = Yes; 2 = NA)	Did event reappear after reintroducing medication? (0 = No; 1 = Yes; 2 = NA)
1.	__/___/__	__/___/__										

NON-INVESTIGATIONAL MEDICATION POSSIBLY RELATED TO EVENT

(If more lines needed, please attach required information)

Medication Trade or Generic Name	Date Started (dd/mmm/yy)	Date Stopped (dd/mmm/yy)	DOSING REGIMEN Amount	Units	Freq.	Route of Admin.	Reason for Use (Major Diagnosis)	Action Taken	Is there a reasonable possibility that the event was caused by this medication?	Main Investigator's Opinion	Did event abate after stopping medication?	Did event reappear after reintroducing medication?
1.	__/___/__	__/___/__							1			
2.	__/___/__	__/___/__							1			

OTHER RELEVANT HISTORY

RELEVANT TESTS / LAB DATA

INVESTIGATOR COMMENT:

INVESTIGATOR'S SIGNATURE:

d d m m m y y

MONITOR COMMENT:

Is event possibly related to medication not listed above? ☐ 0 No ☐ 1 Yes, specify in Monitor Comment section above and attach NIM.

MONITOR'S SIGNATURE:

Received date: __/__/__ (d d m m m y y)

SHEET NO. 1

SERIOUS ADVERSE EVENT REPORT FORM
Exposure in Utero - Instructions

Complete and send this form only if applicable.
For multiple pregnancies, complete one form for each fetus/infant.

- **Type of report:** If the exposure in utero is being reported after there is an outcome of the pregnancy check *retrospective to birth.* If the exposure in utero is being reported while pregnancy continues select *prospective to birth.*

- **Date of conception, or estimated date of conception:** Provide an estimate (eg, by ultrasound) of the date of conception.

- **Date of outcome of pregnancy:** Enter the date that pregnancy ended.

- **Relevant medical history related to pregnancy:** indicate in this section any maternal health problems and medications, smoking and alcohol use during this pregnancy, previous pregnancies and outcomes, family history of congenital anomaly and genetic diseases.

- **Gestational period at time of initial exposure:** Provide an estimate of the duration of pregnancy at the time of initial exposure to study medication and indicate whether it is weeks, months or which trimester by ticking one of the three choices.

  EXAMPLE:

  ☐₁ Weeks
  ☐₂ Months
  0 3 ☒₃ Trimester

- **Outcome of pregnancy:** Select all that apply. A *full term live birth* is a live birth at 37 or more weeks of gestation, a *premature live birth* is a live birth less than 37 weeks of gestation, a *stillbirth* is the delivery of a dead child, also known as fetal death, a *miscarriage/abortion* is the premature expulsion from the uterus of the products of conception, the embryo, or of a non-viable fetus (less than 20 weeks gestation).

- **Any perinatal problems?** If yes, specify any maternal problems that may have occurred between 28 weeks of gestation and 4 weeks after birth (eg, polyhydramnios, abruptio placenta, placenta previa, postpartum hemorrhage, etc.)

- **Outcome of newborn:** Provide APGAR scores at 1, 5, and 10 minutes. Also indicate whether infant was normal, or had a congenital or other anomaly and specify.

- **Newborn Information:** Enter information on sex, weight, length, and gestational age at birth or other outcome in this section.

- **Additional Information / Comments:** If necessary, provide additional maternal or infant information, here.

SERIOUS ADVERSE EVENT REPORT FORM

Exposure in Utero *(Complete and send only if applicable)*

CAREFULLY READ THE INSTRUCTIONS PRIOR TO FILLING IN THE FORM

Protocol No.:

Center No.: _____ **Patient Initials:** _ _ _ **Patient No.:** _____

Type of report: ☐1 Retrospective to birth
☐2 Prospective to birth

First day of last menstrual period:

y y y y - m m - d d

Date of conception, or estimated date of conception:

y y y y - m m - d d

Date of outcome of pregnancy:

y y y y - m m - d d

Relevant medical history related to pregnancy:

Gestational period at time of initial exposure: __ __
☐1 Weeks
☐2 Month
☐3 Trimester

Outcome of pregnancy:
☐1 Full term live birth
☐2 Premature live birth
☐3 Stillbirth
☐4 Congenital anomaly
☐5 Neonatal death
☐6 Miscarriage/spontaneous abortion
☐7 Induced/elective abortion

Any perinatal problems?
☐0 No
☐1 Yes, specify: _____
_____

Outcome of newborn:
APGAR score at 1 minute: __ __
APGAR score at 5 minutes: __ __
APGAR score at 10 minutes: __ __
☐0 Normal
☐1 Congenital anomaly, specify: _____
_____
☐2 Other anomaly, specify: _____
_____

Newborn Information:
Sex: ☐1 Male
☐2 Female

Weight at birth: __ __ __ __ grams

Length at birth: __ __ . __ ☐1 cm ☐2 in

Gestational age: __ __ weeks

Additional Information / Comments:

This section for ı use only

Database No.:

Local Reference No.:

- *Study Termination* refers to the end of study medication period. It is not meant for temporary withdrawal or for the end of follow-up or observation period.
- Tick only one option for the patient disposition.
- Always refer back to the *Study Medication* record and double check the day of last study medication. This date must be in accordance with other visit dates (ie, not be before the first visit or after the last visit).
- If the patient did NOT complete the treatment period as defined in the study protocol, choose one primary reason for withdrawal. Try to find out what lies behind the withdrawal, eg, why a consent was withdrawn or a protocol violation happened. Do not enter that cause on this form, but keep it ready for review. Do not be too quick to enter "Lost to follow-up", patients sometimes return.
- Always choose the most severe reason. Example: If the patient withdrew the informed consent and had side effects that caused problems, tick "Adverse event".
- Termination: The *Study Termination* page must be completed and submitted for all patients who were randomized/assigned study medication.

STUDY TERMINATION (Module 1) (fixed)

*Choose **one** of the following alternatives to describe the patient disposition:*

☐1 Randomized but has not taken any study medication

☐2 Randomized and has taken at least one dose of study medication ⟶ Date of last dose of study medication: __ __ __ __ - __ __ - __ __
y y y y m m d d

Did the patient complete the treatment/study medication period? ☐1 Yes

☐0 No

If No, choose **one** primary reason for withdrawal:

☐1 Adverse event ⟶ **Fill in / update *Adverse Event* page**

☐2 Protocol violation

☐3 Consent withdrawn

☐4 Lost to follow-up

☐5 Protocol specific withdrawal criteria

STUDY TERMINATION (Module 2) (Fixed & Optional)

Date of Assessment: __ __ __ __ - __ __ - __ __
y y y y m m d d

*Choose **one** of the following alternatives to describe the patient disposition:*

☐1 Randomized but has not taken any study medication

☐2 Randomized and has taken at least one dose of study medication ⟶ Date of last dose of study medication: __ __ __ __ - __ __ - __ __
y y y y m m d d

Time of last dose of study medication: __ __ : __ __
(0001-2400)

Did the patient complete the treatment/study medication period? ☐1 Yes
☐0 No

If No, choose **one** primary reason for withdrawal:

☐1 Adverse event ⟶ **Fill in / update *Adverse Event* page**
☐2 Protocol violation
☐3 Consent withdrawn
☐4 Lost to follow-up
☐5 Protocol specific withdrawal criteria
☐6 Progression of disease
☐7 Improvement

STUDY TITLE:

XXXX COMPLETION REPORT

DO NOT WRITE IN SHADED AREAS

PLEASE PRINT

PRINCIPAL INVESTIGATOR	INVESTIGATOR'S NO.	SUBJECT'S INITIALS	SUBJECT NUMBER

PROTOCOL NO.	STUDY PERIOD	DATE OF EVALUATION
__/__ __ __ __/__ __ __ __		d d / m m m / y y (e.g. 01 / MAR / 94)

Date of last dose of investigational medication XXXX: d d / m m m / y y START TIME: (0001-2400) STOP TIME: (0001-2400)

Did this subject complete XXXX?

- ☐ Yes
- ☐ No

If NO, check the primary reason below.

CHECK ONLY ONE

- ☐ Lack of efficacy
- ☐ Improvement

ADVERSE EVENT(S)

- ☐ Death of subject
- ☐ Adverse Event(s) -- serious*
- ☐ Adverse Event(s) -- non-serious

→ Also complete an ADVERSE EVENT FORM (AEF)

ADMINISTRATIVE

- ☐ Subject ineligible for protocol but investigational medication was started
- ☐ Protocol noncompliance other than entry criteria
- ☐ Subject's personal request (unrelated to an Adverse Event or any of the other listed reasons)
- ☐ Subject lost to follow-up
- ☐ Other

→ Also EXPLAIN BELOW

EXPLANATION / COMMENTS

* *SERIOUS = Death, life-threatening, requires or prolongs in-patient hospitalization, persistent or significant disability/incapacity, permanent impairment of function or permanent damage to a body structure or requires intervention to prevent permanent impairment or damage, congenital anomaly/birth defect, or any other adverse event that the investigator or company judges to be serious or which is defined as serious by the regulatory agency in the country in which the adverse event occurred.*

***NOTE:** If any adverse event is still ongoing at this time, its resolution should be recorded on an Adverse Event Form during a subsequent visit or on a Post-Study Follow-up of Adverse Event form.*

I verify that all case report forms completed to date accurately display the results of examinations, tests, and evaluations performed on this subject.

INVESTIGATOR'S SIGNATURE:	d d / m m m / y y
MONITOR REVIEW BY: y y / m m m / d d	SHEET NO.

STUDY TITLE

POST-STUDY FOLLOW-UP OF ADVERSE EVENT

Use this form to report the course of any unresolved serious adverse event (AE) or a non-serious AE assessed by the investigator as possibly related to investigational medication from the end of the reporting period until the AE resolves or is determined to be chronic or stable.

DO NOT WRITE IN SHADED AREAS

PI-0040-0 1/96

PLEASE PRINT

PRINCIPAL INVESTIGATOR	INVESTIGATOR'S NO.	SUBJECT'S INITIALS	SUBJECT NUMBER
	___ ___ ___	___ ___ ___	___ ___ ___ ___ ___ ___

PROTOCOL NO. ___ / ___ ___ ___ ___ / ___ ___ ___ ___

DATE OF EVALUATION: ___ ___ / ___ ___ ___ / ___ ___ (d d / m m m / y y) (e.g. 01/OCT/94)

PLEASE ANSWER ALL QUESTIONS - USE ONE FORM FOR EACH ADVERSE EVENT

1. Identify AE being followed: (Use same terminology as used on the last Adverse Event Form (AEF))

START DATE: ___ ___ / ___ ___ ___ / ___ ___ (d d / m m m / y y)

2. Did this AE resolve since the last report?

☐₁ Yes, Date resolved: ___ ___ / ___ ___ ___ / ___ ___ (d d / m m m / y y)

Were there any residual effects? ☐₀ No ☐₁ Yes - explain:

☐₀ No, Has the AE become chronic or stable since the last report?

☐₀ No*

☐₁ Yes

* This form should be submitted every time a change in this subject's status occurs until AE has resolved or has been determined to be chronic or stable.

3. Did this AE require medical intervention since the last report?

☐₀ No

☐₁ Yes - describe:

4. Did this AE require or prolong hospitalization since the last report?

☐₀ No

☐₁ Yes - describe:

5. Did this subject die?

☐₀ No

☐₁ Yes - specify: Date of death ___ ___ / ___ ___ ___ / ___ ___ (d d / m m m / y y) Primary cause

AUTOPSY ☐₁ Report attached ☐₂ Report pending ☐₃ Report not obtainable ☐₀ Autopsy not done

COMMENTS:

INVESTIGATOR'S SIGNATURE: ___ ___ / ___ ___ ___ / ___ ___ (d d / m m m / y y)

MONITOR REVIEW BY: ___ ___ / ___ ___ ___ / ___ ___ (d d / m m m / y y)

SHEET NO. 1

STUDY SPECIFIC DATA

STUDY TITLE

MICROBIOLOGY REPORT

93-0000-00

DO NOT WRITE IN SHADED AREAS

PRINCIPAL MONITOR	PRINCIPAL INVESTIGATOR	INVESTIGATOR'S NO.	SUBJECT'S INITIALS	SUBJECT NO.
		_ _ _ _ _	_ _ _	_ _ _ _ _

PROTOCOL NO.

SPECIMEN SOURCE CODE

1. _____ 4. _____
2. _____ 5. _____
3. _____ 6. _____

Date Taken (MO. / DAY / YR.) _ _ / _ _ / _ _ Study Period _____

Source: _____ (use code above, if provided)

ORGANISM(S) ISOLATED enter genus and species	ORGANISM CODE	Pathogen? 0 = No 1 = Yes	β-lactamase activity 0 = Neg 1 = Pos 2 = Not Tested	QUANTITY *	ANTIBIOTIC #1 MIC (µg/ml)	ANTIBIOTIC #1 __µg-DISK ZONE (mm)	ANTIBIOTIC #2 MIC (µg/ml)	ANTIBIOTIC #2 __µg-DISK ZONE (mm)
1.								
2.								
3.								
4.								

If no organism specified, check most appropriate reason:

† ☐ 0 No organisms isolated
† ☐ 1 No organisms isolated or normal flora only
☐ 2 Specimen collection not indicated
☐ 3 Specimen not obtained
☐ 4 Specimen not satisfactory

Gram's Stain:
☐ 1 Not Done
☐ 2 Negative
☐ 3 Gram + cocci
☐ 4 Gram + rods
☐ 5 Gram - cocci
☐ 6 Gram - rods
☐ Other (specify): _____

Date Taken (MO. / DAY / YR.) _ _ / _ _ / _ _ Study Period _____

Source: _____ (use code above, if provided)

ORGANISM(S) ISOLATED enter genus and species	ORGANISM CODE	Pathogen? 0 = No 1 = Yes	β-lactamase activity 0 = Neg 1 = Pos 2 = Not Tested	QUANTITY *	ANTIBIOTIC #1 MIC (µg/ml)	ANTIBIOTIC #1 __µg-DISK ZONE (mm)	ANTIBIOTIC #2 MIC (µg/ml)	ANTIBIOTIC #2 __µg-DISK ZONE (mm)
1.								
2.								
3.								
4.								

If no organism specified, check most appropriate reason:

† ☐ 0 No organisms isolated
† ☐ 1 No organisms isolated or normal flora only
☐ 2 Specimen collection not indicated
☐ 3 Specimen not obtained
☐ 4 Specimen not satisfactory

Gram's Stain:
☐ 1 Not Done
☐ 2 Negative
☐ 3 Gram + cocci
☐ 4 Gram + rods
☐ 5 Gram - cocci
☐ 6 Gram - rods
☐ Other (specify): _____

COMMENTS:

* 3 choices are available for quantity

QUANTITY	QUANTITY 1 = Few 2 = Mod 3 = Many	QUANTITY 1 = $< 10^3$ 2 = 10^3 - 10^5 3 = $> 10^5$
_•_ x 10^{-}		
_•_ x 10^{-}		
_•_ x 10^{-}		
_•_ x 10^{-}		

† Choose only one

INITIALS / SIGNATURE:

(On treatment examination)

CLINICAL EVALUATION
Change from Pretreatment

- ☐ 1 Cured
- ☐ 2 Improved
- ☐ 3 Unchanged
- ☐ 4 Worsened
- ☐ 96 Not Applicable

(End of therapy examination)

CLINICAL EVALUATION

- ☐ 1 Cured
- ☐ 2 Improved
- ☐ 3 Failed
- ☐ 5 Failed due to medical event(s)
- ☐ 94 Not assessed / not assessable
- ☐ 96 Not Applicable

(Follow-up examination)

CLINICAL EVALUATION

- ☐ 1 Cured
- ☐ 2 Improved
- ☐ 3 Recurred / Reinfected
- ☐ 94 Not assessed / not assessable
- ☐ 96 Not Applicable

(Follow-up examination)

CLINICAL EVALUATION
Recurrence / Reinfection?

- ☐ 0 No
- ☐ 1 Yes
- ☐ 94 Not assessed / not assessable
- ☐ 96 Not Applicable